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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/782,714	02/13/2001	Seth A. Darst	IPT-011.02	2009

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FOLEY HOAG, LLP
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EXAMINER

BORIN, MICHAEL L

ART UNIT	PAPER NUMBER
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1631

11

DATE MAILED: 07/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/782,714

Applicant(s)

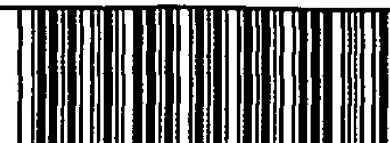
Darst et al

Examiner

Michael Borin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 9, 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 21, and 22 is/are pending in the application.
- 4a) Of the above, claim(s) 21 and 22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other: _____

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DETAILED ACTION

Status of Claims

1. Response to restriction requirement filed 4/9/03 is acknowledged. Applicant elected, with traverse, Group I, claims 1-8. Applicant argues that search of both groups will not place an undue burden. Examiner disagrees. Crystals of Group I are not necessarily produced by method of Group II, and a reference teaching a RNAP of, e.g., claim 1 (which is not drawn specifically to bacterial RNAP), will not teach or suggest a particular method of making of Group II. The restriction requirement is still deemed proper and is therefore made FINAL. Claims 21,22 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected groups. Cancellation of claims 21,22 is requested.

Abstract

2. The abstract of the invention is not descriptive. The abstract does not reflect the elected invention. A new abstract is required which are clearly indicative of the invention to which the elected claims are directed.

Drawings

3. The drawings are approved by Draftsman.

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Claim Rejections - 35 USC § 112, first paragraph.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-3,5-8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the crystal of *Thermus aquaticus* bacterial core RNA polymerase, which crystal effectively diffracts X-rays for determination of the atomic coordinates to a resolution of better than 3.5Å, does not reasonably provide enablement for crystal of any other bacterial or other source core RNA polymerase suitable for same resolution determinations.

The breadth of the claims encompasses crystals of core RNA polymerase from any other bacterial or other source. The only crystal demonstrated to enable the required X-ray diffraction is the crystal of *Thermus aquaticus* bacterial core RNA polymerase. Although there is a general guidance regarding preparation of core RNA polymerase crystals from other bacterial sources (note that claims 1,5-8 are not even limited to bacterial RNA polymerase) informing that the crystals can be grown by a number of conventional techniques, there is no clear teaching on how to arrive at crystals with the required X-ray quality. The specification does not enable any person

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skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

5. Claim 6 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not demonstrate crystal of a core RNA polymerase having ω subunit.

Claim Rejections - 35 USC § 102 and 103.

The following is a quotation of the appropriate paragraphs of 35 U.S.C.102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1,5-7 are rejected under 35 U.S.C. 102(b) as anticipated by Jeruzalmi et al. (J. Mol. Biol. 274 (5), 748-756, 1997).

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Jeruzalmi teaches crystals of bacteriophage T7 suitable for structure detection by X-ray crystallography. Form I of the crystal diffracts x-rays to 3.5 Å, and synchrotron wiggler radiation to 3.2 Å.

7. Claims 1-3,5-7 are rejected under 35 U.S.C. 102(b) as anticipated by Polyakov et al. (Cell, 83, 365-373, 1995). The reference teaches crystal of bacterial RNA polymerase having $\alpha\alpha\beta\beta'$ subunits. The referenced crystal reads on the instantly claimed crystal. Note that the claimed limitations regarding intended use for determination of atomic coordinates is an intended use limitation, not limitation of the size of the crystal, and suggested use limitations do not impart patentability to product claims where the product is otherwise anticipated by the prior art. *In re Pearson*, 494 F.2d 1399, 181 USPQ 641 (CCPA 1974).

8. Similarly, claims 1,2,5,7 are rejected under 35 U.S.C. 102(a) as anticipated by Darst et al (J. Struct. Biol., 124, 115-122, 1998; different inventive entity). The reference teaches crystal of *E. Coli*. RNA polymerase having $\alpha\alpha\beta\beta'$ subunits. The referenced crystal reads on the instantly claimed crystal. Note that the claimed limitations regarding intended use for determination of atomic coordinates is an intended use limitation, not limitation of the size of the crystal, and suggested use

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limitations do not impart patentability to product claims where the product is otherwise anticipated by the prior art. *In re Pearson*, 494 F.2d 1399, 181 USPQ 641 (CCPA 1974).

Conclusion.

No claims are allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703) 305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (703) 308-4028. The fax telephone number for this group is (703) 305-3014.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



MICHAEL BORIN, PH.D
PRIMARY EXAMINER

July 10, 2003

mlb